**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF VIRGINIA**
**Richmond Division**

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| DR. TIMOTHY BAXTER,<br><br>Plaintiff,<br><br>v.<br><br>XAVIER BECERRA, in his official capacity as SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, and<br><br>CHRISTI A. GRIMM, in her official capacity as INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES,<br><br>Defendants. | ) | Civil No. 3:23-cv-92-RCY |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

Defendants Xavier Becerra, in his official capacity as Secretary, Department of Health and Human Services, and Christi A. Grimm, in her official capacity as Inspector General, Department of Health and Human Services, pursuant to the Court's February 8, 2023 Order (ECF No. 19) and Local Rules 7(F) and 56, respectfully submit this memorandum in support of Defendants' Cross-Motion for Summary Judgment and in opposition to Plaintiff Dr. Timothy Baxter's motion for summary judgment (ECF No. 22).

## INTRODUCTION

On August 31, 2020, Plaintiff Dr. Timothy Baxter pleaded guilty under 21 U.S.C. § 331(a) to introducing misbranded drugs into interstate commerce. Dr. Baxter formerly served as the global medical director of Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), a pharmaceutical company that developed and marketed two drugs that assisted with opioid addiction treatment. In this role, Dr. Baxter admitted that he failed to prevent or correct a subordinate's misrepresentations about pediatric safety data in the course of marketing RBP's drugs to the Massachusetts Medicaid program ("MassHealth").

As Dr. Baxter acknowledged in his plea agreement, his conviction came with a collateral civil consequence, that is, exclusion from the ability to participate in federal healthcare programs. The Office of Inspector General for Health and Human Services ("HHS-OIG"), which is charged with exercising the exclusion authority of the Department of Health and Human Services ("HHS"), properly examined the underlying facts of Dr. Baxter's conviction and correctly determined that they mandated exclusion under the statute.

Dr. Baxter now challenges the factual and legal basis for his mandatory exclusion, argues that a single case with different facts compels a different outcome, and seeks to have this Court impose an inapplicable standard of review to HHS-OIG's determination, but none of these arguments have merit. In short, because HHS-OIG's determination that Dr. Baxter's conviction

fell under the mandatory provisions of the exclusion statute enjoys support of both the law and the record, it is entitled to deference, and Defendants are entitled to summary judgment.

## STATUTORY AND REGULATORY BACKGROUND

42 U.S.C. § 1320a-7 authorizes, and in some cases *requires*, that certain individuals and entities be excluded from participating in federal health care programs. The statute specifically requires the Secretary to exclude individuals that have been convicted of certain enumerated offenses. *See id.* § 1320a-7(a). Relevant here, the HHS Secretary "shall" exclude "[a]ny individual or entity that has been convicted of a criminal offense related to the delivery of an item or service" under Medicare or "under any State health care program." *Id.* § 1320a-7(a)(1); *see also* 42 C.F.R. § 1001.101. For such mandatory exclusions, the statutory minimum exclusion period is five years. 42 U.S.C. § 1320a-7(c)(3)(B). The statute also enumerates grounds for permissive exclusion (*i.e.*, exclusion at the discretion of the HHS Secretary). *Id.* § 1320a-7(b). The permissive exclusion period is three years unless the Secretary determines (pursuant to published regulations) that specific mitigating or aggravating circumstances apply. *Id.* § 1320a-7(c)(3)(D). An excluded individual or entity is entitled to notice, the ability to appeal the exclusion through an administrative process, and judicial review once the administrative proceedings are complete. *Id.* § 1320a-7(f).

The HHS Secretary has delegated responsibility for implementing exclusions to HHS-OIG. 48 Fed. Reg. 21662 (May 13, 1983). HHS-OIG notifies individuals subject to the five-year mandatory exclusion through a written notice, which sets out, among other things the basis, length, and effect of the exclusion, as well as an individual's appeal rights. 42 C.F.R. § 1001.2002. The exclusion begins 20 days after the date of the notice. *Id.* § 1001.2002(b). An excluded individual or entity has the right to appeal the exclusion and request a hearing before an ALJ within 60 days of receiving the notice of exclusion. *Id.* § 1001.2007. After the ALJ issues a

final decision, an excluded individual may seek review before HHS's Departmental Appeals Board ("DAB"), and then ultimately may seek judicial review. 42 U.S.C. §§ 405(g), 1320a-7(f).

## STATEMENT OF UNDISPUTED MATERIAL FACTS[1]

### I. RBP's Suboxone Tablets

1. The background for this case involves two drugs manufactured by RBP that received U.S. Food and Drug Administration ("FDA") approval in October 2002: the Suboxone Sublingual Tablet ("Suboxone Tablet") and the Subutex Sublingual Tablet ("Subutex Tablet") (collectively, the "Tablets"). AR[2] 540 ¶ 10.[3]

2. Both drugs came in tablet form and contained buprenorphine, an opioid partial agonist and Schedule III controlled substance, and were designed to treat opioid addiction and dependence. AR 540 ¶ 10.

3. The FDA also approved orphan-drug exclusivity for both Tablets, meaning that it would not approve any competing buprenorphine application for the same indication for seven years. AR 540 ¶ 10.

### II. Dr. Baxter's Career at RBP/Indivior and the Suboxone Film

4. Dr. Baxter became RBP's global medical director in 2006. AR 54. Among other responsibilities, he oversaw RBP's "medical information group," "a team of medical

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[1] Defendants agree with Dr. Baxter that this case will be decided on the administrative record, and therefore the "entire case on review is a question of law and only a question of law," so there should be no disputed facts. *See Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Nevertheless, Defendant submits its statement of undisputed material facts here in accordance with E.D. Va. Local Rule 56(B). Defendants do not dispute Dr. Baxter's statement of facts, though they do disagree with how Dr. Baxter characterizes the Information, Pl.'s Mem. at ¶¶ 4-6, which is contained in the record and speaks for itself, AR 540-47.

[2] All references to "AR" are to the Administrative Record, filed at ECF Nos. 20 and 21.

[3] In his plea agreement, Dr. Baxter admitted that "all of the facts set forth in the Information are true and correct." AR 550.

professionals who were charged with answering medical questions about pharmacology, and medical affairs activities." AR 454 ¶ 15. Dr. Baxter thus "advise[d]" people with authority to make commercial decisions "regarding medical issues and patient safety." AR 454 ¶ 16.

5. One product for which Dr. Baxter "provided medical advice in support of the RBP's research and development efforts" was a potential replacement for the Tablets called Suboxone Film. AR 7; *see* AR 541. ¶¶ 13-14. RBP began developing Suboxone Film in 2007, as the Suboxone Tablet and Subutex Tablet neared the end of their exclusivity period. AR 541 ¶ 13.

6. Like the Suboxone Tablet, Suboxone Film combined buprenorphine with naloxone, an opioid antagonist that causes withdrawal symptoms when injected." AR 540-41 ¶¶ 11, 14. The Subutex Tablet did not contain naloxone. AR 541 ¶ 12. As the name suggests, Suboxone Film was not a tablet but rather a film formulation with some patented elements. AR 541 ¶ 14. Suboxone Film also came packaged in individually wrapped foil pouches, while the Tablets usually came in bottles with child-resistant caps. AR 541 ¶¶ 11-12, 14.

7. Suboxone Film obtained FDA approval in August 2010. AR 541 ¶ 15. At that time, it, along with the Tablets, generated nearly all of RBP's revenue, but after Suboxone Film received FDA approval, RBP only actively promoted Suboxone Film. AR 542 ¶ 19.

8. Dr. Baxter approved a contract with the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") in June 2012 to analyze exposure data from poison control centers regarding the risk of unintended pediatric exposure for buprenorphine drugs. AR 542-43 ¶¶ 18, 22. Dr. Baxter directly managed the RBP employee who was RADARS' point of contact for its pediatric exposure analysis in 2012, RBP's Medical Affairs Manager, Dr. Jane Ruby. AR 542 ¶ 18; AR 254.

9. RBP used RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film. AR 542 ¶ 19.

## III. Dr. Baxter's October and November 2012 Failure to Prevent and Promptly Correct the Distribution of False and Misleading Data to MassHealth

10. In September 2012, Dr. Ruby informed Dr. Baxter that a MassHealth representative had requested a meeting. AR 543 ¶ 23.

11. At the time, MassHealth had the largest volume of business for addiction-treatment drugs of any Medicaid program—but it did not list Suboxone Film as a preferred drug on its formulary and restricted approval of Suboxone Film for reimbursement. AR 542 ¶ 20.

12. With an opportunity to potentially expand Suboxone Film's presence in the MassHealth market, Dr. Ruby stated that she was excited "to share the pediatric data" RADARS had gathered with the official. AR 543 ¶ 23. She assured Dr. Baxter that "things will change in Massachusetts." AR 543 ¶ 23.

13. Dr. Ruby met with MassHealth's Pharmacy Director Dr. Paul Jeffrey on October 9, 2012. AR 543-44 ¶ 24; AR 254. Dr. Ruby reported to Dr. Baxter that Dr. Jeffrey was "very responsive" to the pediatric-exposure data. AR 543-44 ¶ 24. Dr. Ruby advised Dr. Baxter that she had asked RADARS for a Massachusetts-specific analysis of unintended pediatric exposure that she could send to MassHealth and opined that her expectation was that exposure rates would track the "high" "utilization of tablets" in Massachusetts. AR 543-44 ¶ 24. Dr. Baxter was copied on Dr. Ruby's email to RADARS. *United States v. Baxter*, No. 1:20cr32 (W.D. Va.), ECF No. 64-29 at 1-2.

14. On October 10, 2012, RADARS responded with the requested data. AR 544 ¶ 25. Contrary to Dr. Ruby's expectation, Suboxone Film did not have the lowest exposure rate—instead, it was sandwiched between Suboxone Tablets (highest) and buprenorphine only tablets,

which had the lowest rate of unintended pediatric exposure. AR 544 ¶ 25.

15. If the exposure rates for the two forms of Tablets were added, however, the combined-tablet-rate appeared higher than Suboxone Film's exposure rate. AR 544 ¶ 25. Dr. Ruby asked RADARS, again copying Dr. Baxter, whether she could simply "add the [Tablets' rates] to see the difference from [Suboxone Film]." AR 544 ¶ 26.

16. Dr. Baxter himself responded to this email, observing that RADARS's data "actually appear[ed] to make [Subutex Tablets] look best or am I mi[s]-reading?" AR 544-45 ¶ 26. RADARS told Dr. Ruby, copying Dr. Baxter, that they would follow up with the additional calculations sought. AR 544 ¶ 26.

17. Nevertheless, in an October 16, 2012 email, Dr. Ruby combined the Tablets' exposure rates as she had proposed and sent that data to MassHealth's Dr. Jeffrey, representing to MassHealth that Suboxone Film had a lower pediatric-exposure rate than the Tablets. AR 545 ¶ 27. It, however, was not accurate to simply add the Tablets' exposure rates together. AR 545 ¶ 27. She also incorrectly stated that this data had come from RADARS, when she had done the calculations herself. AR 545 ¶ 27. Dr. Ruby forwarded her email to Dr. Baxter noting "hope" that this would "help us get some movement in Mass." AR 544 ¶ 27. Dr. Baxter did not respond to this email. AR 544 ¶ 27.

18. On November 19, 2012, Dr. Ruby responded to a follow-up question from MassHealth's Dr. Jeffrey about Dr. Ruby's October 16 email by sending him a chart comparing pediatric-exposure rates of Suboxone Film and Suboxone Tablets. AR 545-46 ¶ 28. The chart contained data lines only for "Tablets" and "Oral Film"; a third data line pertaining to buprenorphine-only tablets (*e.g.*, Subutex), which had a rate much closer to that of Suboxone Film, was omitted. AR 545-46 ¶ 28.

19. This chart thus reinforced the incorrect representation in Dr. Ruby's October 16 email that Suboxone Film had the lowest rate of unintended exposure in the state. AR 545-46 ¶ 28. Combined with the previous misleading email, the chart "failed to reveal facts material to MassHealth prior to its updated formulary decision." AR 545-46 ¶ 28. Around the same time, another employee emailed Dr. Baxter asking whether they could use a similar chart that likewise omitted the data regarding buprenorphine-only tablets and commenting how its use "would make such a huge difference!" AR 545-46 ¶ 28. Dr. Baxter replied that "[t]hat chart is now published so [k]nock yourself out!" AR 545-46 ¶ 28. Dr. Ruby subsequently received data that also did not show that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts, but she did not share that data with the Dr. Jeffrey at MassHealth. AR 546 ¶ 29.

20. In December 2012, MassHealth announced that it would provide access to the unit-dose formulation of Suboxone Film for households with children under six years old. AR 546-47 ¶ 30.

21. Dr. Baxter did not approve sending a correction letter to MassHealth until 2015—three years after the misrepresentations. AR 547 ¶ 31.

22. RBP demerged from its parent company, Reckitt Benckiser Group, and became Indivior Inc. ("Indivior"), a subsidiary of Indivior PLC, in December 2014. AR 538 ¶ 3. Dr. Baxter then became Indivior PLC's chief medical officer, a role he held until he left in May 2016. AR 538 ¶ 3.

## IV. Dr. Baxter's Conviction Under 21 U.S.C. § 331(a)

23. In August 2020, Dr. Baxter, as a responsible corporate officer, pleaded guilty in the United States District Court for the Western District of Virginia to one misdemeanor count of misbranding a drug in violation of 21 U.S.C. § 331(a). AR 549-59; *United States v. Baxter*, No. 1:20cr32 (W.D. Va.). The criminal charge was based on the series of false and misleading

statements regarding Suboxone Film made by Dr. Baxter's direct subordinate, Dr. Ruby, to MassHealth's pharmacy director, Dr. Jeffrey, in October and November 2012, and Dr. Baxter's failure to prevent and promptly correct those false and misleading statements. AR 542-47.

24. As part of his plea agreement, Dr. Baxter acknowledged that he could be "excluded pursuant to 42 U.S.C. § 1320a-7 from participation in Medicare, Medicaid, and all other Federal health care programs." AR 553.

25. Dr. Baxter was sentenced to one year of probation, with six months to be served in home confinement, and the statutory maximum $100,000 fine. AR 562, 565. At sentencing, Dr. Baxter's counsel acknowledged that they likely would "spend[] the first part of next year arguing about whether or not he should be excluded." AR 607:10-110.[4]

**V. Dr. Baxter's Exclusion Under to 42 U.S.C. § 1320a-7(a)(1)**

26. In a May 27, 2021 letter, HHS-OIG notified Dr. Baxter that HHS-OIG proposed to exclude him from participation in federal health programs pursuant to 42 U.S.C. § 1320a-7(a) "[a]s a result of [his] conviction in the United States District Court, Western District of Virginia." AR 779.

27. The notice advised that Dr. Baxter had 90 days to submit information and supporting documentation in support of a response to the proposed exclusion. AR 779.

28. Dr. Baxter submitted his response, and HHS-OIG considered the information furnished. AR 535. HHS-OIG issued a notice of exclusion on September 30, 2021, notifying Dr. Baxter that effective 20 days later, he would be excluded from Medicare, Medicaid, and all federal health care programs for five years pursuant to § 1320a-7(a)(1) due to his conviction of a

[4] Indivior was the subject of federal criminal and civil investigations for its marketing of Suboxone, resulting in its pleading guilty to one count of making false statements relating to health care matters and paying $600 million in criminal and civil penalties, restitution, and forfeitures. *United States v. Baxter*, No. 1:20cr32 (W.D. Va.), ECF No. 64-14 at 3.

criminal offense related to the delivery of an item or service under Medicare or a State health care program. AR 535.

29. Dr. Baxter requested a hearing before an Administrative Law Judge ("ALJ"). Neither party proposed any witnesses and both parties indicated that a hearing was not necessary to the resolution of the matter. AR 2.

30. An ALJ from the HHS Departmental Appeals Board ("DAB") affirmed the IG's exclusion determination, concluding that Dr. Baxter's conviction was related to the delivery of a health care item or service under the Medicaid program, and thus he was subject to a mandatory five-year exclusion from federal health care programs. AR 1-17.

31. Dr. Baxter appealed that decision to the DAB's Appellate Division, which affirmed the ALJ's decision, again finding that Dr. Baxter had been convicted of a criminal offense related to the delivery of an item or service under a state health care program, which warranted the imposition of a five-year mandatory exclusion. AR 18-50.

32. On November 22, 2022, Dr. Baxter filed this civil action challenging the DAB's final decision. *See* Compl. (ECF No. 1).

## STANDARD OF REVIEW

### I. Review under 42 U.S.C. § 405(g)

Dr. Baxter seeks review under 42 U.S.C. § 405(g),[5] which allows any individual to obtain

[5] Dr. Baxter properly invoked 42 U.S.C. § 405(g) and 42 U.S.C. § 1320a-7(f), which provide the jurisdictional basis for this Court's review of the DAB's decision. His arguments in his brief, however, center on the Administrative Procedure Act ("APA") standard of review. The Secretary disputes this reliance and maintains that the appropriate standard of review is that of § 405(g). Courts have consistently held that § 1320a-7(f), which incorporates §§ 405(g) and 405(h), is the sole standard of judicial review of final decisions of the Secretary. *See Rudman v. Leavitt*, 578 F. Supp. 2d 812, 814 (D. Md. 2008); *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 14 (2000); *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984); *Weinberger v. Salfi*, 422 U.S. 749, 763-65 (1975); *Hindley v. Dep't of Health & Human Servs.*, 2015 WL 8753266, at *4 (N.D. Cal. Dec. 15, 2015). Moreover, § 405(h) specifically states that "[n]o action against the United States,

judicial review of the "final decision" of the HHS Secretary after all administrative proceedings have been exhausted. *See* 42 U.S.C. § 1320a-7(f); *id.* at § 405(g); Compl. (ECF No. 1); *see also Ram v. Heckler*, 792 F.3d 444, 446 (4th Cir. 1986) ("Physicians suspended from the [M]edicare program" may seek "judicial review of the 'final decision'" of the HHS Secretary after administrative proceedings have been exhausted.). Specifically, under § 405(g), a district court may review the Secretary's "final decision . . . made after a hearing" to determine whether that decision is supported by "substantial evidence" and whether the Secretary applied the correct legal standards. 42 U.S.C. § 405(g); *see also Hays v. Sullivan*, 907 F.2d 1453, 1456 (4th Cir. 1990). Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (internal citations omitted). If substantial evidence supports the Secretary's decision, then the Secretary's findings "shall be conclusive." 42 U.S.C. § 405(g); *see also Hancock v. Astrue*, 667 F.3d 470, 472 (4th Cir. 2012) (In reviewing for substantial evidence, the Court may not reweigh the evidence, try the case de novo, make credibility determinations, or

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the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." *See also Parrino v. Sebelius*, No. 3:14-cv-00038-H, 2014 WL 10743300 (W.D. Ky. Mar. 19, 2014) ("[w]hile 28 U.S.C. § 1331 grants the court jurisdiction over all 'civil actions arising under the Constitution, laws or treaties of the United States,' it does not independently waive the Government's sovereign immunity; § 1331 will only confer subject matter jurisdiction where some other statute provides such a waiver") (citing *High Country Citizens Alliance v. Clarke*, 454 F.3d 1177, 1181 (10th Cir. 2006)). Even if the Court were to review this action under the APA, the outcome should be the same because the difference between the substantial evidence standard and the APA's arbitrary and capricious standard on which Dr. Baxter relies is "largely semantic." *Akinjiola v. Holder*, No. ELH–12–2597, 2014 WL 641702, at *6 (D. Md. Feb. 14, 2014); *Friedman v. Sebelius*, 686 F.3d 813, 826 (D.C. Cir. 2012); *Begum v. Hargan*, No. 16 CV 9624, 2017 WL 5624388, at *4 (N.D. Ill. Nov. 21, 2017) ("the Court notes, however, that when it affirms the Secretary's decision under the standards of the SSA . . . the Court also finds that the decision should stand under the APA. Judicial review of agency action under the APA is narrow, and courts must limit their review of the agency's action to the administrative record before the agency"); *Fuentes v. Becerra*, No. 4:20-CV-00026, 2021 WL 4341115, at *7 (W.D. Va. Sept. 23, 2021).

substitute its judgment for that of the Commissioner.).

## II. Review under the Administrative Procedure Act

The Administrative Procedure Act ("APA"), 5 U.S.C. § 701, *et seq.*, provides the statutory basis for a court to review a final agency action. A court may only set aside a final agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An action is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Review "is highly deferential," and there is a "presumption in favor of finding the agency action valid." *Ohio Valley Envtl. Coal v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009). The court "must defer to the agency if its action has a rational basis." *Am. Meat Inst. v. U.S. Dep't of Agric.*, 646 F.2d 125, 127 (4th Cir. 1981). Thus, the court reviews only "whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment." *Holly Hill Farm Corp. v. United States*, 447 F.3d 258, 263 (4th Cir. 2006).

# ARGUMENT

## I. Substantial Evidence Supports Dr. Baxter's Mandatory Exclusion

### A. 42 U.S.C. § 1320a-7(a)(1) mandated Dr. Baxter's exclusion

Section 1320a-7(a) reflects a congressional judgment that if any individual is convicted of a specific subset of criminal offenses, that individual *must* be excluded from participating in federal health care programs for the statutory minimum five-year term. 42 U.S.C. § 1320a-7(a). As the Fourth Circuit has observed, the statute serves dual purposes: "combat[ting] waste, fraud,

and abuse in health insurance and health care delivery" and "provid[ing] a clear and strong deterrent against the commission of criminal acts." *Morgan v. Sebelius*, 694 F.3d 535, 538 (4th Cir. 2012) (quoting Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996); S. Rep. 100-109, *reprinted in* 1987 U.S.C.C.A.N. 682, 686 (noting intended deterrent effect of mandatory exclusion for program-related crimes)). Specifically, under § 1320a-7(a)(1), the Secretary "shall exclude" any "individual . . . that has been convicted of a criminal offense related to the delivery of an item or service under . . . any State health care program."

In a 33-page final decision, the appellate division of the DAB upheld Dr. Baxter's mandatory exclusion under § 1320a-7(a) because the record showed that he had been convicted of a criminal offense related to the delivery of Suboxone Film to MassHealth. That decision enjoys support of both the law and the record and should be affirmed for the reasons set forth below.

### B. The Secretary's decision was consistent with 42 U.S.C. § 1320a-7(a)(1) and with HHS regulations, precedent, and practice

Dr. Baxter argues that the Secretary's decision to exclude him was "an unjustified departure from HHS practice" and thus was arbitrary and capricious. Pl.'s Mem. (ECF No. 23) at 24-27 (capitalization removed). That argument is incorrect.

The Secretary's decision to exclude Dr. Baxter was *not* a "departure from long standing regulatory practice." Pl.'s Mem. at 24 (quotation marks and citation omitted). Federal agencies "'are under an obligation to follow their own regulations, procedures, and precedents.'" *Jewell Smokeless Coal Corp. v. Looney*, 892 F.2d 366, 368 n.5 (4th Cir. 1989) (quoting *Nat'l Conservative Pol. Action Comm. v. Fed. Election Comm'n*, 626 F.2d 953, 959 (D.C. Cir. 1980)) (alteration removed)). The Secretary did that here.

Consistent with 42 U.S.C. § 1320a-7(a)(1), HHS's regulations state that the Secretary

"will exclude any individual or entity that . . . [h]as been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program." 42 C.F.R. § 1001.101. The DAB has long held that an offense is "related to" the delivery of an item or service under a covered program if there is "some nexus or common[-]sense connection between the offense . . . and the delivery of an item or service" under that program. *Lyle Kai, R. Ph.*, DAB No. 1979, 2005 WL 1540186, *3 (H.H.S. June 15, 2005); *James O. Boothe*, DAB No. CR2770, 2013 WL 3439790, *7 (H.H.S. May 1, 2013) (citing *James R. Benham*, DAB No. 2042, 2006 WL 2751078, *5 (H.H.S. Sept. 14, 2006)). In analyzing whether the requisite nexus or common-sense connection exists, "evidence as to the nature of an offense may be considered," such as the facts and circumstances upon which the conviction was predicated. *Kai*, DAB No. 1979 at *3.

Under that approach, the facts and circumstances of Dr. Baxter's misdemeanor misbranding conviction demonstrate a clear nexus between his conviction and the delivery of an item under MassHealth. Suboxone Film is a health care item used in the treatment of opioid addiction and is paid for by MassHealth. AR 541. Dr. Baxter's direct subordinate, Dr. Ruby, made false and misleading statements to MassHealth's Dr. Jeffrey about the safety of Suboxone Film. AR 545-547. Dr. Baxter, "as a responsible Indivior executive, failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth." AR 547 ¶ 32. And the record shows that MassHealth decided to expand coverage based on that false and misleading data. *See, e.g.*, AR 664, 666, 675 (Dr. Jeffrey's testimony in which he stated that the false data and incomplete graph Dr. Baxter's subordinate, Dr. Ruby, sent "mattered to him."), AR 645 ("MassHealth's pharmacy director also emailed his supervisor, the director of MassHealth, stating that he relied on the Massachusetts-specific data Indivior sent him."), AR 689 (MassHealth's pharmacy director stated that they

ultimately "made a change in [their] policy around Suboxone Film . . ." and the data provided by Indivior "was the pivot point upon which we made that decision"). Indeed, the Information's factual summary involves marketing communications between Indivior personnel and MassHealth regarding Indivior's drugs. AR 542-48. The record thus provides substantial support for the Secretary's conclusion that Dr. Baxter's conviction is "related to" the delivery of an item or service under MassHealth, and therefore falls under mandatory exclusion.

And Dr. Baxter's mandatory exclusion in these proceedings is not an anomaly. The Secretary has repeatedly excluded under § 1320a-7(a)(1) individuals convicted of misdemeanor misbranding based on the individual facts and circumstances of each case. *See, e.g.*, *Shaun Thaxter*, DAB No. 3053, 2021 WL 7451237 (H.H.S. Dec. 29, 2021) (mandatory exclusion for an RCO misbranding conviction); *Vincent Koh, M.D.*, DAB No. CR5262, 2019 WL 3210562 (H.H.S. Mar. 5, 2019); *Eduardo Miranda, M.D.*, DAB No. 2755, 2016 WL 8732017 (H.H.S Dec. 22, 2016); *Mohamed Basel Aswad*, M.D., DAB No. 2741, 2016 WL 8732003 (H.H.S. Oct. 18, 2016), aff'd *Aswad v. Hargan*, No. 2:16-CV-1367-BRB-SMV, 2018 WL 704370 (D.N.M. Feb. 2, 2018); *Leo Parrino*, DAB No. 2587, 2014 WL 5319648 (H.H.S. Aug. 4, 2014), aff'd *Parrino v. Price*, 869 F.3d 392, (6th Cir. 2017); *Christopher Keegan*, DAB No. CR3242, 2014 WL 2804177 (H.H.S. May 27, 2014). Significantly, in the related case of Shaun Thaxter—Indivior's CEO who was similarly convicted of RCO misdemeanor misbranding—the DAB concluded that "[p]resenting false information to a state Medicaid agency so that it pays for the drugs your company manufactures and sells is plainly 'related to' the delivery of an item under a state health care program" and stated that "this is not a close case." *Thaxter*, 2021 WL 7451237, at *8 & *10.

The Secretary followed its statutory directive, regulations, and principles, as the DAB's decision makes clear. AR 33-43. Dr. Baxter nonetheless makes three arguments for why the

Secretary departed from its "longstanding . . . practice." Pl.'s Mem. at 24. Each of those arguments should be rejected.

**1. *Friedman v. Sebelius* does not establish any "long standing practice" that bars the Secretary's mandatory-exclusion decision**

First, Dr. Baxter's reliance on (only) *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012), as establishing that "long standing . . . practice" fails. Pl.'s Mem. at 24.[6] Neither the *Friedman* decision nor the Secretary's brief established that "strict liability convictions for RCO misdemeanor misbranding [are] subject to permissive exclusion." Pl.'s Mem. at 24. *Friedman* instead expressly affirmed the same practice used here: a "circumstance-specific approach" that "authorizes exclusion of an individual whose conviction was for conduct factually related to," 686 F.3d at 820, relevant here, "the delivery of an item or service . . . under any State health care program," 42 U.S.C. § 1320a-7(a)(1); *see* AR 33-34; *Friedman*, 686, F.3d at 820 ("the text, structure, and purpose of the statute . . . to protect Federal health care programs from financial harm wrought by untrustworthy providers, all indicate the Secretary's circumstance-specific approach is proper.").

And even if *Friedman* had established a long-standing practice and even if the Secretary had departed from it, the Secretary "provide[d] a reasoned explanation for" the departure, *Jimenez-Cedillo v. Sessions*, 885 F.3d 292, 298 (4th Cir. 2018), by correctly distinguishing *Friedman*. AR 43-44. As an initial matter, Dr. Baxter's cited portion, Pl.'s Mem. at 25, of the Secretary's *Friedman* brief addressed only whether, under the aggravating factor in 42 C.F.R. § 1001.201(b)(2)(i), the "convictions caused losses to federal and state governments far exceeding

[6] Dr. Baxter's analysis of "related to" has nothing to do with the threshold question of which of mandatory or permissive exclusion applies; both statutes use "related to." 42 U.S.C. § 1320a-7(a)(1) ("criminal offense related to the delivery of an item or service"); *id*. § 1320a-7(b)(1)(A) ("consisting of a misdemeanor relating to fraud").

$5,000," *Friedman*, Appellant's Br., 2011 WL 5240481, *48, and not whether the offenses "related to . . . any State health care program" under § 1320a-7(a)(1). The *Friedman* plaintiffs' misdemeanor misbranding conviction was based on "their admitted failure to prevent Purdue's fraudulent marketing of OxyContin" generally. *Friedman*, 686 F.3d at 816. Dr. Baxter's conviction in contrast was based on his failure to prevent and promptly correct false statements made directly to MassHealth, a Medicaid program, to get a drug approved for Medicaid beneficiaries' purchase and use; his Information references MassHealth many times, *see* AR 542-47 ¶¶ 20, 23-24, 27-32, while the criminal information in *Friedman* lacked *any* allegation that the misbranded products had a connection to Medicare or any state health program. *See* Information, *United States v. Perdue Frederick Co.*, No. 1:07-cr-29 (ECF No. 5) (W.D. Va. May 10, 2007), at 1-16. So the Secretary reasonably distinguished *Friedman* from Dr. Baxter's case on the basis that the former "did not involve an entity's direct misrepresentations to a state Medicaid program, so that the program would expand access to its misbranded drug" and the misbranding there "was not directed at any particular health care plan." AR 43. *Friedman* therefore does not undermine Dr. Baxter's mandatory exclusion, as the facts and circumstances underlying his conviction support his exclusion under § 1320a-7(a)(1).

Dr. Baxter's *Friedman*-based arguments about the Secretary's supposed departure from established practice belie his actual argument: the court should overrule his mandatory exclusion in favor of permissive exclusion regardless of *his conviction's* facts and circumstances. That argument is essentially asking the court to improperly "substitute its judgment for that of the agency." *Judulang v. Holder*, 565 U.S. 42, 53 (2011) (quotation marks and citations omitted). But where the facts and circumstances support a mandatory exclusion, the Secretary has no discretion to consider permissive exclusion. 42 U.S.C.§ 1320a-7(a)(1) ("The Secretary shall

exclude"). Because the facts and circumstances here support Dr. Baxter's mandatory exclusion, his arguments should be rejected

**2. Restitution is not required for 42 U.S.C. § 1320a-7(a)(1) mandatory exclusion**

Second, Dr. Baxter argues that the Secretary "failed to justify his application of mandatory exclusion in the absence of any restitution payment." Pl.'s Mem. at 25. That argument should be rejected. Section 1320a-7(a)(1) does not require restitution and does not require any loss amount, as the Secretary correctly reasoned below. AR 44. Indeed, as the DAB has previously found, "the offense need not have actually harmed the program in any way" for § 1320a-7(a)(1) exclusion to apply. *James O. Boothe*, DAB No. 2530, 2013 WL 5310192, *3 (H.H.S. Aug. 21, 2013); *Paul R. Scollo*, DAB No. 1498, 1994 WL 808216, *5 (H.H.S. Sept. 30, 1994) ("There is no requirement that there be harm to Medicare or Medicaid in order for a conviction to be related to the delivery of items or services under one or both programs within the meaning of section 1128(a)(1) [42 U.S.C. § 13270a-7(a)(1)]."). There is thus no "long standing practice" that § 1320a-7(a)(1) applies only where there is restitution.

**3. The absence of losses or victims does not make Dr. Baxter's offense "unrelated" to MassHealth**

Third, it does not "undermine the statutory basis" for mandatory exclusion that "the presentence report indicated that there were no losses or victims associated with Dr. Baxter's conduct." Pl.'s Mem. at 27. The DAB properly rejected Dr. Baxter's continued attempts to read into § 13270a-7(a)(1) "requirements that are not contained in the literal language of the law." AR 43. Section 1320a-7(a)(1) requires only "a criminal offense related to the delivery of an item . . . under any State health care program;" it does not require losses or victims. And Dr. Baxter's Information states that he "failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth." AR 547 ¶

32. The Secretary below rightly found that, applying the circumstance-specific approach to "related to," Dr. Baxter's offense qualified for mandatory exclusion.

**4. The facts and circumstances of Dr. Baxter's conviction mandate his mandatory exclusion under § 1320a-7(a)(1), so the issue of permissive exclusion is moot**

Finally, because the facts and circumstances of Dr. Baxter's misdemeanor misbranding conviction show that it was related to the delivery of Suboxone Film to MassHealth, § 1320a-7(a)(1) mandates his exclusion, so the issue of permissive exclusion is moot. Dr. Baxter argues that because his conviction could conceivably fall under permissive exclusion, it cannot qualify as mandatory. Pl.'s Mem. at 20. That analysis has it backward. An exclusion determination under § 1320a-7 is a "two-step process." *Travers v. Sullivan*, 801 F. Supp. 394, 404 (E.D. Wash. 1992), aff'd sub nom *Travers v. Shalala*, 20 F.3d 993, 405 (9th Cir. 1994). The Secretary first considers whether a conviction meets the requirements of *mandatory* exclusion under § 1320a-7(a). *Id.* "If the prerequisites of this section are met, the Secretary is directed by Congress to exclude that individual, and the issue of permissive exclusion becomes moot. It is *only after* the Secretary determines that the individual's conviction was not for a 'program-related crime' that the permissive exclusion statute becomes relevant." *Id.* (emphasis added). This means, "where a conviction triggers both the mandatory (section 1128(a)) and permissive (section 1128(b)) exclusion provisions, the Secretary . . . is required to implement the mandatory exclusion." ¶ 300,141 *James Randall Benham*, DAB CR1405 (2006), aff'd, DAB No. 2042 (2006) (citing Healthcare Compl. Rep. P 300141 (citing DAB decisions recognizing that, where "a conviction triggers both the mandatory (section 1128(a) [§ 1320a-7(a)(1)]) and permissive (section 1128(b) [§ 1320a-7(b)(1)(A)]) exclusion provisions, the Secretary does not have discretion as to which provision to impose. The Secretary is required to implement the mandatory exclusion.").

Dr. Baxter relies on *Leddy v. Becerra* for his argument that the Secretary should have first determined whether his conviction falls under permissive exclusion before assessing mandatory exclusion, Pl.'s Mem. 20-21, but that case has no application here. There, Dr. Leddy had been convicted of obstructing a potential Medicare audit. *Leddy v. Becerra*, --- F. Supp. 3d ----, 2022 WL 2978620, *1 (E.D.N.Y. July 28, 2022). The *Leddy* court applied permissive exclusion there because § 1320a-7 has a provision that *specifically* calls for permissive exclusion for a conviction "in connection with the interference with or obstruction of any investigation or audit." 42 U.S.C. § 1320a-7(b)(2)(ii); *Leddy*, 2022 WL 2978620, *6 (citing *id*.). In light of that express statutory language, the court applied the well-established interpretive principle that the "specific governs the general" and held that permissive exclusion must apply. *Leddy*, 2022 WL 2978620, *6. No such specific provision applies to Dr. Baxter's misbranding conviction.

**C. The Secretary's decision is supported by the record**

**1. The Secretary's decision is consistent with the evidence before the agency**

Dr. Baxter's primary basis for his argument that HHS-OIG's determination is unsupported by the record stems from his misplaced reliance on the December 2012 MassHealth prescriber letter. Pl.'s Mem. at 27-29 (citing AR 440). Dr. Baxter argues that the letter establishes that MassHealth only considered accurate national data, but the facts do not support this. Pl.'s Mem. at 27 (citing AR 440 & n.1, 546-47). And the DAB correctly rejected that argument, recognizing that "MassHealth never 'stated that it relied solely on the accurate data," and that the December 2012 letter "did not purport to catalog all the information MassHealth considered in reaching its decision." AR 36.

The Information, and thus the Secretary's decision, did not rely solely on the December 2012 letter. As the DAB noted, Dr. Baxter was convicted "despite MassHealth's reference to

nationwide pediatric exposure data in its December 2012 letter" and "it was his failure to prevent or promptly correct Indivior's dissemination of false and misleading state-specific data to MassHealth that led to [Dr. Baxter's] misbranding conviction." AR 36 (citing AR 547 ¶ 32). The Secretary thus concluded that "a common-sense nexus between [Dr. Baxter's] misbranding offense and the delivery of Suboxone Film under the MassHealth program [wa]s amply supported." AR 36. That "offered . . . explanation for its decision" does not "run[] counter to the evidence before" HHS. *State Farm*, 463 U.S. at 43.

**2. Dr. Jeffrey's testimony confirms that MassHealth's December 2012 expansion was related to Dr. Baxter's offense**

Dr. Baxter's argument that the Secretary erred in citing the testimony of MassHealth's Pharmacy Director, Dr. Jeffrey, because that testimony "confirms that MassHealth's expansion decision was unrelated to the misbranding," Pl.'s Mem. at 28, likewise should be rejected.

As the DAB found, AR 37-38, the October 2012 RADARS data "showed that buprenorphine-only tablets … had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts, " AR 38 (quoting AR 544 ¶ 25). Dr. Baxter's subordinate Dr. Ruby, however, when emailing Dr. Jeffrey in October 2012 "added the [buprenorphine-only tablet and Suboxone Tablet] rates together," which did "not provide an accurate calculation;" "indicated to [Dr. Jeffrey] that she had received the calculations from RADARS when, in fact, she had not received them from RADARS, but had done the calculations herself;" and "stated to [Dr. Jeffrey] in the email . . . that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts" while knowing that information to be false. AR 545 ¶ 27. As the DAB correctly concluded, then, "the data for buprenorphine-only tablets that Indivior concealed from MassHealth was not only relevant, but directly contradicted Indivior's assertion that Suboxone Film had the lowest rate of unintended pediatric exposure." AR 38. And as Dr. Jeffrey

stated, the correct data (that is, the RADARS data) "'absolutely' mattered to him, and if [Dr. Ruby] had sent the data showing that film had a greater rate of pediatric exposure than tablets (which includes buprenorphine-only tablets), then [Dr. Jeffrey] would have 'stopped any process to change [MassHealth's] policy decision around the film.'" AR 38 (quoting AR 690-91). And contrary to Dr. Baxter's argument, Pl.'s Mem. at 29 (quoting AR 691), what Dr. Jeffrey did not "know if it would have a made a change in the decision," *id*., was the "difference of 2.7 for Suboxone film versus 3.3 for Suboxone tablets," not the combined-tablet-number, and in any event, he testified that the 2.7-to-3.3 difference "would have mattered," AR 691. Moreover, Dr. Baxter's reference to a 2013 study that showed that "exposure to the film was not, in fact, greater than the exposure to the tablet," Pl.'s Mem. at 29 & 6 n.2, is irrelevant. The nexus to MassHealth is the October and November 2012 data and communications, as set forth above.

Nor did the DAB "err[] in admitting" Dr. Jeffrey's testimony "because Dr. Baxter had no opportunity to cross-examine Dr. Jeffrey." Pl.'s Mem. at 28. Dr. Baxter had the right to request a hearing, 42 C.F.R. § 1005.2(1), present and cross-examine witness, *id*. § 1005.3(a), and move the ALJ to issue a subpoena to any such witness, *id*. § 1005.9(a). Dr. Baxter did not do so despite being "aware that the [Secretary] intended to rely on the transcript of Dr. Jeffrey's testimony," as the DAB correctly found, AR 29-30, and thus had the "reasonable notice" that "clearly expresse[s] or strongly implie[s]" waiver for failure to cross-examine Dr. Jeffrey, *Wallace v. Bowen*, 869 F.2d 187, 193 (3d Cir. 1989). And *Wallace* and *Mase*, Pl.'s Mem. at 28, do Dr. Baxter no good; both address cross-examination of "post-hearing" witnesses. *Wallace*, 869 F.2d at 193-94 ("Waiver of the right to subpoena and cross-examine witnesses concerning post-hearing evidence must be clearly expressed or strongly implied from the circumstances. In light of the lack of any provision in the regulations for a subpoena under these circumstances and the

failure to notify Wallace's counsel that there was an option to subpoena the consultative witnesses, counsel did not receive the type of reasonable notice that could serve as the predicate for a waiver."); *Mase v. Comm'r of Soc. Sec.*, No. CV 21-10024 (JXN), 2022 WL 1184801, at *3 (D.N.J. Apr. 21, 2022) ("In *Wallace*, the Third Circuit held that when an administrative law judge chooses to go outside the testimony adduced at the hearing in making a determination on a social security claim, the ALJ must afford the claimant not only the opportunity to comment and present evidence but also an opportunity to cross-examine the authors of any post-hearing reports when such cross-examination is necessary to the full presentation of the case, and must reopen the hearing for that purpose if requested.").

**3. There was a delivery of Suboxone Film to MassHealth**

Dr. Baxter argues that § 1320a-7(a)(1)] requires the Secretary to prove that MassHealth paid for prescriptions to establish that there was a delivery. Pl.'s Mem. at 29. That argument is incorrect, as the DAB rightly found. AR 39. And *Friedman* does not say otherwise. Pl's Mem. at 29 (citing *Friedman*, 686 F.3d at 825). Dr. Baxter's cited *Friedman* language was addressing the aggravating factor analysis about financial harm to a program, 42 C.F.R. § 1001.201(b)(2)(i), which is irrelevant for determining whether there was a delivery to a program. *See Friedman*, 686 F.3d at 825; *see also* AR 13, 39, 138, 195; *see supra* Section I.A1 & *infra* n.11.

Nor does MassHealth's January 2016 decision regarding Suboxone Film's formulary placement negate delivery or have any relevance to the question of whether Dr. Baxter's criminal offense for the October and November 2012 misstatements relate to the delivery of Suboxone Film to MassHealth at that time. Pl.'s Mem. at 29. As the DAB correctly found, Dr. Baxter's "criminal information [] makes no mention of MassHealth's January 2016 decision regarding Suboxone Film or the drug's current preferred status;" rather, "it was MassHealth's decision in December 2012 to expand access to Suboxone Film for members living in households with

children under six years of age that formed the predicate for [Dr. Baxter's] misbranding conviction" and the nexus for § 1320a-7(a)(1). AR 31.

Review under the APA is "highly deferential, with a presumption in favor of finding the agency action valid," *Ohio Valley*, 556 F.3d at 192, and an agency need only articulate a "rational connection between the facts found and the choice made," *State Farm*, 463 U.S. at 43 (quotation marks and citation omitted). The Secretary met that standard here.

## II. Dr. Baxter's Asserted Heightened Standard of Review Does Not Apply

### A. The major questions doctrine does not apply

In an attempt to overcome the highly deferential standard of review that applies in this case, Dr. Baxter invokes the "major questions doctrine," which, if it applied, would require this Court to find "clear Congressional authorization" for the Secretary's exercise of its exclusion authority. *See* Pl.'s Mem. at 17 (quoting *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. 661, 665 (2022)). That doctrine, however, is wholly inapplicable here.[7]

As the Supreme Court has explained, the "major questions doctrine" is reserved for "extraordinary cases" in which "the history and the breadth of the authority that [the agency] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority." *West Virginia v. E.P.A.*, 142 S. Ct. 2587, 2608 (2022) (applying the major questions doctrine to EPA's interpretation of a statute that would "empower[] it to substantially restructure the American energy market" through "vague language of an 'ancillary provision[]'") (internal quotations omitted). As the Court has explained, the doctrine only applies when an agency reads into an "ambiguous statutory text" authority to assert "highly consequential power beyond what

[7] Dr. Baxter did not raise this argument at the administrative stage.

Congress could reasonably be understood to have granted," or "extravagant statutory power over the national economy." *Id.* at 2609. In other words, short of an agency action that "would bring about an enormous and transformative expansion in [the agency's] regulatory authority without clear congressional authorization," the major questions doctrine does not apply. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014).

This case, unlike those on which Dr. Baxter relies, does not ask whether the Secretary interpreted § 1320a-7(a)(1) to allow it to undertake wholly new regulatory powers. Rather, this case raises the routine question of whether the Secretary correctly applied mandatory exclusion—a power that Congress unambiguously and indisputably granted to HHS, which HHS is *required* to impose in applicable circumstances, and which HHS has exercised for *decades*—to a single individual. This case thus presents circumstances that are a far cry from the "extraordinary" circumstances required for the major questions doctrine to apply.

**B. Dr. Baxter has not established any due process issue**

Dr. Baxter argues that this case falls within the major questions doctrine because of the purported constitutional implications of the exclusion. Pl.'s Mem. at 14-15. Simply because a plaintiff asserts a constitutional challenge to an agency action does not render a case "extraordinary," and the case Dr. Baxter cites is not to the contrary. *Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 540 (D.C. Cir. 2020) (applying major questions doctrine to a statutory construction that "would seem to give [the agency] unbridled power to promulgate any regulation with respect to drug manufacturers that would have the arguable effect of driving down drug prices—or even healthcare costs generally"); Pl.'s Mem. at 14 (citing *Merck & Co.*). But in any event, Dr. Baxter's exclusion does not raise a due process issue.

Dr. Baxter has not asserted the due process on which he proceeds. Compl. at 19; Pl.'s Mem. at 14-15. But in any event, to advance a due process claim, a plaintiff must first "establish

that he had a property or liberty interest at stake." *Smith v. Ashcroft*, 295 F.3d 425, 429 (4th Cir. 2002). The Fourth Circuit has recognized a medical provider's property interest in continued participation in federal health programs, *see Ram v. Heckler*, 792 F.3d 444, 447 (4th Cir. 1986),[8] but Dr. Baxter's argument that he has a liberty interest in pursuing his chosen profession faces a steeper challenge. "[A]ll cases recognizing such a right have 'deal[t] with a *complete prohibition* on the right to engage in a calling, and not [a] sort of brief interruption.'" *Guzman v. Shewry*, 552 F.3d 941, 954 (9th Cir. 2009) (quoting *Conn v. Gabbert*, 526 U.S. 286 (1999)) (emphasis in original); *id*. at 954-55 (holding that physician's indefinite exclusion from state Medicaid program did not "deprive[ him] of a protected liberty interest in pursuing the occupation of his choice"); *see also Parrino v. Price*, 869 F.3d 392, 398 (6th Cir. 2017) (to establish a deprivation of a "protected liberty interest in the employment context, a plaintiff must demonstrate stigmatizing governmental action which so negatively affects his . . . reputation that it effectively forecloses the opportunity to practice a chosen profession" and that "the stigmatizing information was publicly disclosed") (quotation marks and citations omitted). Despite his generalized allegations about the potential effects of exclusion, Dr. Baxter has not alleged or established that he has been foreclosed from practicing his chosen profession—working in the pharmaceutical

[8] *Ram*'s conclusion in this respect relied on *Bowens v. North Carolina Department of Human Resources*, 710 F.2d 1015, 1018 (4th Cir. 1983), which held that a dentist had a property right in continued participation in a North Carolina health program based on language in a *state* administrative regulation expressly creating such an interest. The *Bowens* court specifically held that the plaintiff had "a property right *under North Carolina law*," which does not apply here. *Id.* at 1017. Nevertheless, because *Ram* applied the *Bowens* holding, without analysis, in circumstances similar to those presented here, Defendants acknowledge that it governs whether Dr. Baxter has a property right in his continued participation in Medicare. Defendants note, however, that the other Circuit courts to have considered the question have reached the opposite conclusion. *See Parrino*, 869 F.3d 392 (*citing Erickson v. U.S. ex rel. Dep't of Health & Human Servs*., 67 F.3d 858, 862 (9th Cir. 1995)); *Koerpel v. Heckler*, 797 F.2d 858, 863-65 (10th Cir. 1986); *Cervoni v. Sec'y of Health, Ed. & Welfare*, 581 F.2d 1010, 1018-19 (1st Cir. 1978)).

industry—despite now having been excluded for nearly 18 months. AR 535.[9]

No matter the theory on which Dr. Baxter proceeds, as the DAB correctly recognized, *see* AR 49-50, the D.C. Circuit has already considered and roundly rejected the precise argument that Dr. Baxter has made, that is, that somehow due process places limitations on his exclusion from federal health programs because of a strict liability offense, *see* Compl. ¶¶ 80-83. As the D.C. Circuit explained in *Friedman*, "we do not think excluding an individual under 42 U.S.C. § 1320a-7(b) on the basis of his conviction for a strict liability offense raises any significant concern with due process." 686 F.3d at 824. The Court went further, noting "[e]xclusion effectively prohibits one from working for a government contractor or supplier. Surely the Government constitutionally may refuse to deal further with senior corporate officers who could have but failed to prevent a fraud against the Government on their watch." *Id.*

**C. Dr. Baxter's exclusion follows the plain language of the statute**

Because the major questions doctrine simply does not apply here, the Court need not find "clear congressional authorization" for the Secretary's authority to implement a mandatory

[9] Even if Dr. Baxter has an interest in continued participation in federal healthcare programs, that interest is limited. Multiple courts have held that a physician's interest in receiving government reimbursement for treating patients whose medical expenses are covered by such programs is limited at best. A medical provider "is not the intended beneficiary of the Medicare program." *Northlake Cmty. Hosp. v. United States*, 654 F.2d 1234, 1242 (7th Cir. 1981). Further, "a provider's financial need to be subsidized for the care of its Medicare patients is only 'incidental to the purpose and design of the (Medicare) program.'" *Id.* (quoting *Geriatrics, Inc. v. Harris*, 640 F.2d 262 (10th Cir. 1981)); *see also, e.g.*, *Ritter v. Cohen*, 797 F.2d 119, 123 (3d Cir. 1986) (holding that individual doctor whose practice consisted of ninety-nine percent Medicaid patients "d[id] not merit as great a protection" since "he may seek private patients" and could obtain reimbursement if he was successful in his post-deprivation appeal); *Blue Valley Hosp., Inc. v. Azar*, 322 F. Supp. 3d 1149, 1166-67 (D. Kan. 2018) (holding that the interest of a provider facing exclusion "is not particularly compelling because a Medicare provider is not the intended beneficiary of the program"), aff'd 919 F.3d 1278 (10th Cir. 2019). This is doubly true here, where Dr. Baxter does not treat *any* patients—he does not have a license to practice medicine in the United States, AR 607:19-20, and rather has worked as a corporate executive and consultant, AR 252.

exclusion; regardless, such authorization is plainly set forth in the statute. Section 1320a-7(a) expressly *requires* HHS to exclude "from participation in any Federal health care program" "any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service" under Medicaid or "any State health care program." 42 U.S.C. § 1320a-7(a), (a)(1). Although Dr. Baxter argues that the statute cannot bear a reading that encompasses his misdemeanor misbranding offense within this provision, Pl.'s Mem. at 17-19, this is incorrect, *see supra* Section I.A-C.

In *Parrino v. Price*, 869 F.3d 392 (6th Cir. 2017), the Sixth Circuit rejected a challenge to a mandatory exclusion by a pharmacist who had pleaded guilty to introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. § 331(a)—precisely the crime to which Dr. Baxter pleaded guilty. *Id.* at 395. The court held that the plaintiff's mandatory exclusion "complied with the statutory language" and accepted the proposition that certain individual misdemeanor misbranding offenses might be subject to permissive exclusion, while others may be properly subject to mandatory exclusion where the underlying facts and circumstances support it. *Id.* at 400. Dr. Baxter's conviction falls within the latter category. *See supra* Section I.A-C.

Dr. Baxter next challenges the Secretary's application of a circumstance-specific analysis, as opposed to a categorical one, to determine whether a particular offense falls within mandatory or permissive exclusion. Pl.'s Mem. at 18-20. But, as the DAB properly found, *see* AR 32 n.15, this argument has been roundly rejected by the D.C. Circuit in a detailed discussion in *Friedman*. There, the court rejected as "crabbed and formalistic" the plaintiffs' argument that their misdemeanor misbranding conviction must be analyzed through the categorical, as opposed to the circumstance-specific, approach. *Friedman*, 686 F.3d at 820. The court concluded that the

phrase "fraud . . . with respect to any act or omission in a program" did not "refer to a generic offense but rather to criminal conduct that, as a matter of fact, relates to a program financed by a government agency." *Id.* at 821.

Indeed, relying on Supreme Court authority interpreting the phrase, the *Friedman* court held that the words "relate to" are "deliberately expansive" and "capacious," and accepted HHS's position that a misdemeanor "relates to" something "in the normal sense of the phrase," if it "has a factual connection with" it. 686 F.3d at 820. It thus upheld the use of the circumstance-specific approach in the context of HHS-OIG's decisions regarding exclusion, finding that the statute "unambiguously authorizes her to exclude the [a]ppellants." *Id.*[10] And although the *Friedman* court analyzed § 1320a-7(b)(1), it is a "standard principle of statutory construction . . . that identical words and phrases within the same statute should normally be given the same meaning," *Watson v. United States*, 552 U.S. 74, 81 (2007). As there is no specific crime referenced in § 1320a-7(a)(1), the use of "related to" in that section must be given the same effect. *See also, e.g.*, *United States v. Price*, 777 F.3d 700, 708 (4th Cir. 2015) (explaining that the categorical approach applies when Congress uses words like "element," and when a statute contains language that "refers to specific circumstances or conduct, the Court has determined that Congress meant to allow the circumstance-specific approach's more searching factual inquiry concerning a prior offense").

Dr. Baxter relies on a footnote in one district court case to argue for a different result. Pl.'s Mem. 18-20 (discussing *Kabins v. Sebelius*, No. 2:11–cv–01742–JCM–RJJ, 2012 WL 4498295, at *3 n.1 (D. Nev. Sept. 28, 2012). But the short, paragraph-long discussion of the

[10] Dr. Baxter has not argued that § 1320a-7(a)(1) is ambiguous, but even if it were, courts have afforded *Chevron* deference to the agency with respect to its application of the circumstance-specific standard. *See Bohner v. Burwell*, No. 15-4088, 2016 WL 8716339, at *5 (E.D. Pa. Dec. 2, 2016).

"common sense nexus test" in that case cites no support from case law, is based on entirely different facts, is "dicta at best," *Harkonen v. Sebelius*, No. C-13-0071, 2013 WL 5734918, at *8 (N.D. Cal. Oct. 22, 2013) (discussing *Kabins*), and has not been followed by other courts. *See also* AR 140.

Dr. Baxter also invokes one provision of the Immigration and Naturalization Act to assert that the categorical approach used there applies to all statutes with the phrase "relating to." Pl.'s Mem. at 19. *Friedman* rejected this argument, noting that it "err[s] by focusing narrowly upon the phrase 'relating to' in the INA," as opposed to the surrounding words "law or regulation," which support the use of the categorical approach for that specific statute. 686 F.3d at 823. The court found that analysis inapplicable to the more fact-specific language in § 1320a-7. *Id.* [11] The categorical approach thus does not apply.[12]

[11] Dr. Baxter argues that HHS-OIG's approach is "seemingly . . . incongruent with congressional intent" but does not put forth *any* authority in support. Pl.'s Mem. at 18. By contrast, the legislative history provides otherwise. Over the life of § 1320a-7, Congress has *expanded* both mandatory and permissive exclusion to provide HHS-OIG with additional exclusion authority with respect to mandatory and permissive exclusion, indicating "the express legislative intent to protect federal programs and their beneficiaries from bad actors." *Bohner*, 2016 WL 8716339, at *7 (citing S. Rep. No. 100-109 at *7 (1987)). Before 1987, exclusions under § 1320a-7(a)(1) applied to individuals whose criminal convictions "related to such individual's *participation* in the delivery of medical care or services under title XVIII, XIX, or XX." 42 U.S.C. § 1320a-7(a)(1) (1986). The 1987 amendment expanded the scope of § 1320a-7(a)(1) to apply to offenses "related to the delivery of an item or service under" Medicare or a State health care program. *See* Omnibus Budget and Reconciliation Act of 1980, Pub. L. No 96-499, reprinted in 1980 U.S.C.C.A.N. 5526, 5572. By deleting the word "participation," Congress indicated that it did not want the Secretary to limit exclusion as Dr. Baxter suggests. *See* Pl.'s Mem. at 21; *supra* at Section I.B.1; AR 13, 39 (collecting DAB cases concluding that to require *actual* delivery would reads limitation into § 1320a-7(a)(1) that is not supported by its plain language).

[12] Dr. Baxter argues that the Secretary "essentially confessed . . . legal error" in its position that mandatory exclusion is warranted here, citing a portion of the DAB's opinion. Pl.'s Mem. at 17 n.6. This portion is merely a part of a paragraph in which the DAB explains that the ALJ properly analyzed the facts and circumstances of the case, as opposed to using the categorical approach—a conclusion that accords with the language of the statute and the case law.

## CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court grant their motion for summary judgment and deny Plaintiff's motion for summary judgment.

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Respectfully submitted,

JESSICA D. ABER
UNITED STATES ATTORNEY

By: /s/
JONATHAN T. LUCIER, VSB No. 81303
Assistant U.S. Attorney
Office of the United States Attorney
919 East Main Street, Suite 1900
Richmond, Virginia 23219
Tel.: (804) 819-5400
Fax: (804) 771-2316
Email: jonathan.lucier@usdoj.gov

REBECCA S. LEVENSON
Assistant U.S. Attorney
2100 Jamieson Avenue
Alexandria, Virginia 22314
Tel.: (703) 299-3760
Fax: (703) 299-3983
Email: rebecca.s.levenson@usdoj.gov

*Counsel for Defendants*

OF COUNSEL

Tessa J. Devereaux
Maddie J. Bainer
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

**CERTIFICATE OF SERVICE**

I certify that on March 29, 2023, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to all counsel of record.

/s/

Jonathan T. Lucier, VSB No. 81303
Office of the United States Attorney
919 East Main Street, Suite 1900
Richmond, Virginia 23219
Tel.: (804) 819-5400
Fax: (804) 771-2316
Email: jonathan.lucier@usdoj.gov